

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Tetsuo Kojima et al.	Art Unit :	1646
Patent No. :	7,732,149	Examiner :	Michael D. Pak
Issue Date :	June 8, 2010	Conf. No. :	4551
Serial No. :	10/511,993		
Filed :	March 28, 2005		
Title :	METHODS OF SCREENING FOR AGONISTIC ANTIBODIES		

Commissioner for Patents
P.O. Box 1450
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APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 922 days to 1140 days is respectfully requested.

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. Patentees respectfully submit that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B).

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

Applicant Delay

A reply to an Office Action was due on or before March 13, 2008 (the date that is three months after December 13, 2007, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on June 12, 2008, thereby according an Applicant Delay of 91 days. See 37 C.F.R. § 1.704(b). Patentees do not dispute the PTO’s calculation for this Applicant Delay.

Patentees filed an Information Disclosure Statement on July 23, 2008, subsequent to a reply filed on June 12, 2008. Patentees were accorded a delay of 41 days for a supplemental response. See 37 C.F.R. § 1.704(c)(8). Patentees do not dispute the PTO’s calculation for this Applicant Delay from June 13, 2008, to July 23, 2008.

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: August 9, 2010.

A reply to an Office Action was due on or before February 14, 2009 (the date that is three months after November 14, 2008, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on May 13, 2009, thereby according an Applicant Delay of 88 days. See 37 C.F.R. § 1.704(b). Patentees do not dispute the PTO's calculation for this Applicant Delay from February 15, 2009, to May 13, 2009.

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 220 days.

"A Delay"

A first PTO action was due on or before May 28, 2006 (the date that is fourteen months after March 28, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The PTO mailed the first non-final Office Action on July 6, 2007, thereby according a PTO Delay of 404 days. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1). Patentees do not dispute the PTO's calculation for this "A Delay."

A PTO action was due on or before October 12, 2008 (the date that is four months after June 12, 2008, the date on which a response to Office Action was filed). The PTO mailed a Final Rejection on November 14, 2008, thereby according a PTO Delay of 33 days. See 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2). The PAIR/PALM system does not display this calculation of "A Delay" from October 13, 2008 (the day after the date that is four months after the date on which a response to Office Action was filed), to November 14, 2008; however, the delay was displayed in the PAIR/PALM system at the time of allowance, and it is Patentees' understanding that the delay is not displayed at issuance because it overlaps with another delay.

A PTO action was due on or before September 13, 2009 (the date that is four months after May 13, 2009, the date on which a response to Office Action was filed). The PTO mailed a Notice of Allowability on December 17, 2009, thereby according a PTO Delay of 95 days. See 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2). The PAIR/PALM system does not display this calculation of "A Delay" from September 14, 2009 (the day after the date that is four months after the date on which a response to Office Action was filed), to December 17, 2009; however,

the delay was displayed in the PAIR/PALM system at the time of allowance, and it is Patentees' understanding that the delay is not displayed at issuance because it overlaps with another delay.

In view of the period of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 532 days.

"B Delay"

There is no dispute that the Office failed to issue a patent within three years of the filing date of the application and that Patentees are entitled to "B Delay" to compensate for that Office delay. The only issue in contention is the correct length of the "B Delay" period.

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/JP2003/005372, filed April 25, 2003, which claims the benefit of priority of Japanese Application No. 2002-127260, filed April 26, 2002.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application. As a result, the date that the national stage commenced was October 26, 2004 (i.e., 30 months from the priority date of April 26, 2002).

The period beginning on October 27, 2007 (the day after the date that is three years after October 26, 2004, the date that the national stage commenced), and ending June 8, 2010 (the date the patent was issued), is 956 days in length. The "PTA 36 Months" entry in the PAIR/PALM system indicates that a total of 738 days were awarded for "B Delay" for this patent. Patentees respectfully submit that the PTO's calculation of this "B Delay" is incorrect.

When Does "B Delay" Occur?

As outlined in *Wyeth v. Kappos*, 93 U.S.P.Q. 2d 1257 (Fed. Cir. Jan. 7, 2010, affirming *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008)), the period of "B delay" begins on the day after the date that is three years from the filing of the application and concludes upon the issuance of the patent:

Correspondingly, a violation of the B guarantee—the one at the heart of the issue in this case—begins when the PTO fails "to issue a patent within 3 years after the actual filing date of the application in the United States" *Id.* § 154(b)(1)(B). It ends when "the

patent is issued.” Id. The “period of delay” under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.

Id.

“B Delay” may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In the present matter, no Request for Continued Examination was filed.

Also excluded from the “B Delay” calculation by 35 U.S.C. § 154(b)(1)(B) is “time consumed by appellate review by the Board of Patent Appeals and Interferences.” Id. In the present matter, the Board of Patent Appeals and Interferences (“the Board”) never reviewed an appeal proffered by Patentees.

In the instant case, the entire period beginning on October 27, 2007 (the day after the date on which the national stage commenced), and ending June 8, 2010 (the date the patent was issued) – a period of 956 days – should thus be considered in the calculation of “B Delay.”

How Does Filing a Notice of Appeal Affect “B Delay?”

Properly excluded from a calculation of “B Delay” is “time consumed by appellate review by the Board of Patent Appeals and Interferences.” See 35 U.S.C. § 154(b)(1)(B). As applied by the Office, 37 C.F.R. § 1.703(b)(4) appears to exclude from “B Delay” time periods *not* encompassed by actual appellate review and is therefore inconsistent with the controlling statute. In particular, the Office’s regulation excludes from “B Delay” time starting from when a Notice of Appeal is filed. This reduction of “B Delay” is a clear deviation from 35 U.S.C. § 154(b)(1)(B), as it begins an exclusion before any potential appellate review ever takes place. “Appellate review,” if it ever occurs at all after a Notice of Appeal is filed, cannot occur until jurisdiction passes to the Board of Patent Appeals and Interferences.

By its unambiguous meaning, “appellate review by the Board of Patent Appeals and Interferences” can only occur when the Board reviews an appeal. In this case, a Notice of Appeal was filed on May 13, 2009, the next action issued by the Office was a Notice of Allowability on December 17, 2009, and a Notice of Allowance was mailed on

December 28, 2009. The length of the period from the filing of the Notice of Appeal to the mailing of the Notice of Allowance is 230 days. In this Notice of Appeal period, the Examiner withdrew the final rejections without filing an Examiner's answer. The case never proceeded to the jurisdiction of the Board, the Board never reviewed the case (nor could it without an Examiner's answer), and no decision was ever issued by the Board – either in favor of the Applicant or in favor of the Office. Clearly, no appellate review by the Board occurred after the filing of the Notice of Appeal. No reduction of “B Delay” is provided for by 35 U.S.C. § 154(b)(1)(B) in this instance.

How Is “B Delay” Calculated in the Instant Patent?

The “PTA 36 Months” entry in the PAIR/PALM system indicates that the Office awarded 738 days for application pendency of more than three years (i.e., “B Delay”).

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the period between the filing of a Notice of Appeal and the issuance of a Notice of Allowance must be excluded from the “B Delay” calculation. Yet, no time was actually “consumed by appellate review by the Board of Patent Appeals and Interferences” as provided for in 35 U.S.C. § 154(b)(1)(B).

In view of the foregoing remarks, Patentees respectfully request that this period of time be restored in its entirety to the period of “B Delay.” “B Delay” for this patent is therefore calculated as 956 days. The PTO calculated only 738 days of delay for issuance of a patent more than three years after filing. Patentees respectfully submit that the PTO's calculation of this “B Delay” is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 956 days.

Overlap of “A Delay” and “B Delay”

As detailed above, 532 days of “A Delay” accumulated during the following periods:

May 29, 2006, to July 6, 2007;
October 13, 2008, to November 14, 2008; and,
September 14, 2009, to December 17, 2009.

As detailed above, 956 days of "B Delay" accumulated during the following period:

October 27, 2007, to June 8, 2010.

As such, the periods of "A Delay" and "B Delay" overlap (i.e., occur on the same calendar day) for a total of 128 days, from October 13, 2008, to November 14, 2008, and from September 14, 2009, to December 17, 2009.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentees believe the PTA calculation of 922 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 1360 days (i.e., the sum of 532 days of "A Delay" and 956 days of "B Delay" minus 128 days of overlap);
- 2) Total Applicant Delay should be calculated as 220 days; and
- 3) Total PTA should be calculated as 1140 days.

The fee of \$200 required under 37 C.F.R. § 1.18(e) is being filed herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 14875-0135US1.

Respectfully submitted,

Date: August 9, 2010

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